Health Professionals and AI

PROTOTYPICAL CODE OF ETHICS TO GOVERN AND INFORM PROFESSIONAL PRACTICES

H-pod

AUTHORS

MARCO LAVERDIÈRE

Lawyer, Research Associate of the Canada Research Chair on Collaborative Culture in Health Law and Policy and of the Hub santé - politique, organisations et droit (H-POD) at Université de Montréal, professor in the Master's program in health law and policy at Université de Sherbrooke, Secretary and Director General of the Ordre des optométristes du Québec

CATHERINE RÉGIS

Full professor at Université de Montréal's Faculty of Law, holder of a Canada Research Chair in Health Law and Policy, a Canada-CIFAR Chair in AI, Associate Academic Member at Mila (Quebec AI Institute) and co-director of the Health Hub – Policy, Organization and Law (H-POD)

THIS DOCUMENT WAS ORIGINALLY WRITTEN IN FRENCH AND WAS PUBLICLY RELEASED IN JANUARY 2023. THIS TRANSLATION WAS COMPLETED OVER THE FOLLOWING MONTHS, BUT THE CONTENT HAS NOT BEEN UPDATED AFTER THE INITIAL RELEASE.

ACKNOWLEDGEMENTS

The authors would like to thank all of the Quebec health and human relations professional orders and other stakeholders involved in this project. They would especially like to thank the following individuals for their participation in the working group:

Patrick Boudreault, B.Pharm, M.Sc, LL.B., Director of External Affairs and Professional Support, Ordre des pharmaciens du Québec

Mathieu Corbeil, Professional Affairs Officer, Professional Affairs Branch, Ordre des travailleurs sociaux et des thérapeutes conjugaux et familiaux

Jean-Louis Denis, full professor at the School of Public Health of Université de Montréal, Canada Research Chair in Health Systems Design and Adaptation, regular researcher at the CHUM Research Centre

Julie Gélinas, RN, BScN, MEd, Quality of Practice Advisor, Professional Development and Support Branch, Ordre des infirmières et infirmiers du Québec

Carine Milante, RN, MScN, Practice Quality Advisor, Professional Development and Support Branch, Ordre des infirmières et infirmiers du Québec

Josée Prud'Homme, Adm.A, M.A.P., Executive Director and Secretary, Ordre professionnel des inhalothérapeutes du Québec

Caroline Roy, RN, MScN, Assistant Director, Advanced Nursing Practice and Partner Relations, Professional Development and Support Branch, Ordre des infirmières et infirmiers du Québec

Isabelle Tardif, M.D., CCMF, FCMF, Deputy executive director and secretary, Collège des médecins du Québec (in replacement of Yves Robert, M.D. M.Sc.)

This work was carried out with the financial support of the H-POD and the Canada Research Chair on Collaborative Culture in Health Law and Policy.

Université de Montréal

< >
Montréal Declaration
Responsible AI_
</ >

CHAIRE DE RECHERCHE DU CANADA
sur la culture collaborative
en droit et politiques de la santé

TABLE OF CONTENTS

INTRODUCTION

According to the World Health Organization[1], the potential benefits of AI for patients and communities depend on efforts to develop and implement ethically defensible laws and policies. Sound regulations are needed to ensure that AI is developed and deployed in ways that maximize positive impacts and limit potential harm to patients and stakeholders.

In Quebec and in the other Canadian jurisdictions, regulatory colleges are on the frontlines when it comes to overseeing the use of AI in the health sector. Although they are not governmental bodies per se, these organizations have significant regulatory responsibilities in protecting the public—including the mandate to oversee the professional practice of various healthcare and human relations professionals. Given their proximity to practice and their understanding of the clinical field, regulatory colleges could play a useful role in supplementing the regulatory framework for AI in healthcare.

This is why in 2019, Quebec's regulatory colleges in the healthcare and social services sector joined forces with a group of researchers at the University of Montreal (Prof. Catherine Régis, Marco Laverdière and Prof. Jean-Louis Denis) to reflect on their responsibilities with respect to AI governance. Their reflections focused not only on the normative level but also on how they can better train and support healthcare and social services professionals. They used guiding principles, mainly derived from the *Montreal Declaration for the Responsible Development of Artificial Intelligence*[2], to organize and prioritize proposals for action.

This document is the result of their work. It includes the main findings of the project and, based on these results, it proposes a prototypical code of ethics that could support the successful integration of AI into professional practice. Regulatory colleges and other relevant authorities can draw inspiration from this prototype to develop resources and training activities for their members and ultimately to clarify or update the standards that apply to health professionals using novel technologies like AI.

SECTION 1

REGULATING AI IN HEALTHCARE: DELINEATING STAKEHOLDERS' ROLES

When considering the regulation of AI in healthcare, the first step should be to identify the relevant competent authorities and delineate their mandates. It is worth noting that in Canada, the regulatory responsibilities are quite fragmented due to the separation of legislative powers between federal, provincial and territorial authorities. As a result, certain issues may fall into blind spots that result from the lack of coordination between the stakeholders[3].

HEALTH CANADA

At the federal level, Health Canada is the key player. Its specific mandate is to enforce the *Food and Drugs Act*[4] and the *Medical Devices Regulations*[5]. Under this regulatory framework, medical device manufacturers are subject to various licensing and approval requirements. The stringency of the approval requirements varies according to a risk-based approach. The higher the risks posed by the device, the more stringent the requirements for its approval.

In the healthcare sector, AI algorithms can either be integrated into a specific physical object —such as a device or apparatus with any diagnostic or therapeutic purpose—or exist in a dematerialized state in the form of software[6]. In either case, they could be considered "devices" that must comply with licensing and approval requirements. However, the approval process, and Health Canada's mandate in general, focuses primarily on the safety and efficacy of medical devices. And for now, that mainly means imposing conditions that must be met before the product is introduced on the market. This might be an issue for AI-devices. Indeed, given that certain forms of AI—those that rely on machine learning—continue to evolve autonomously after they are deployed, it is not clear that either the issuance of a license or the approval by Health Canada optimally protects the public. The fact that an AI system (AIS) approved by Health Canada could develop new characteristics after practitioners have started using it raises questions about the relevance of current approval mechanisms. With the rise of AI, ex-ante assessments of risks and benefits might not be sufficient. There may be a need for new oversight modalities that would require assessment of medical devices at different stages of their life cycle[7]. Health Canada is currently considering these issues, as are other similar medical device regulators around the world.

PRIVACY COMMISSIONERS

In addition to Health Canada, privacy commissioners also have a role to play in the governance of AIS used in healthcare. AIS raise significant concerns with respect to the protection of personal information. This responsibility is shared between the federal government[8] and the provinces. Some provinces, such as Quebec, have chosen to enact their own legislation in this area[9]. These laws have recently been updated[10]. It's the Commission d'accès à l'information that is responsible for enforcing them.

At the federal level, the government has introduced a bill that proposes enacting Canada's first piece of legislation dedicated to AI[11]. If passed into law, the bill will create the position of an AI and Data Commissioner. It will also regulate AIS to the extent permitted by the federal government's powers over trade and commerce and criminal matters. Notably, the bill proposes to require specific measures to mitigate risks posed by "high-impact AI systems,"[12]—a term that will be defined through regulations but could likely include various clinical applications of AI in the healthcare sector, notably medical devices[13].

PROVINCIAL GOVERNMENTS

For the most part, provincial governments are responsible for the organization and financing of the health care system. For instance, the Quebec provincial authorities:

- Define and implement the framework that governs how health and social services institutions (hospitals, long-term care facilities, etc.) are organized, operated and financed[14].
- Define and implement the framework that governs the organization and financing of services that fall under the jurisdiction of the Régie de l'assurance maladie du Québec (RAMQ) (physicians and, in certain circumstances, other professionals such as dentists and optometrists)[15].
- Assume other responsibilities, namely those related to hospitalization insurance[16] and prescription drug insurance[17], as well as those related to health information processing[18] and the assessment of innovation and new technologies in health (which is part of the mission of the Institut national d'excellence en santé et en services sociaux (INESSS))[19].

REGULATORY COLLEGES

The regulation of professional practice is a power conferred to the provinces under the Canadian constitution. It is distinct from the provincial power over the healthcare system, although it is closely related[20]. Quebec—and all other Canadian provinces, with some variations—have opted for a model based on self-governance, self-regulation, and collegiality to oversee the practice of health professionals. Regulatory colleges are responsible for carrying out this mandate[21] and they are primarily governed by members of the profession elected by their peers.

While the provinces have delegated regulatory and oversight responsibilities to the regulatory colleges—as well as administrative tribunals for disciplinary matters—they have also retained some control over these organizations. For instance, the Office des professions du Québec's mandate is to ensure that the regulatory colleges carry out their responsibilities of public protection[22].

Given that regulatory colleges have extensive powers over the practice of their members[23], they could play a central role in the regulation of AI, on a wide range of issues: privacy, health care safety and quality, informed consent and the corresponding duty to provide sufficient information, etc. Whether healthcare professionals work in the public or private sector, whether their services are state-funded or not, they remain subject to the relevant professional regulations, and regulatory colleges have the authority to intervene through inspections, investigations, and, if necessary, disciplinary proceedings[24].

However, it would be wrong to assume that the role of regulatory colleges is limited to making regulations and sanctioning their members. Regulatory colleges also play an important role in continuing education[25]. They support their members throughout their careers by offering training activities to help them update their knowledge on various topics, such as the use of emerging technologies. Moreover, regulatory colleges are local actors that interact with their members through conferences and meetings. As such, they are well positioned to identify new or emerging trends in the field. Now, regulatory colleges are not a silver bullet. They cannot be the only cornerstone that supports the whole enterprise of regulating AI in healthcare. AI being sometimes disruptive, it could compromise the interests of a profession—its economic interests, for instance[26]. As a result, some professionals, and even their regulatory colleges might be resistant to AIS integration even when it could benefit the population. Fragmentation is another potential problem with regulatory colleges as a mechanism for regulating AI in healthcare. Several regulatory colleges, each with its own set of regulations, may not be ideal if the goal is a coherent regulatory framework to address AI-related issues in healthcare. And given the limited resources that regulatory colleges have to enforce their regulations, they might not be the most robust apparatus for protecting the public from the proponents of AIS—some of whom are tech Goliaths.

In conclusion, while regulatory colleges have inherent limitations, they can help define and implement AI regulations and support the healthcare professionals who will be required to comply with them. Because of their close ties to their members, they are well positioned to monitor the opportunities and challenges presented by the integration of AI into professional practice and, more broadly, into the healthcare system.

SECTION 2

IDENTIFYING PRIORITIES: SURVEYING QUEBEC'S REGULATORY COLLEGES' ABOUT AI IN HEALTHCARE

In 2019, a group of academics and various representatives designated by regulatory colleges operating in the health and social services sector in Quebec joined forces to work on issues related to the regulation of AI. This prototype code of ethics is the result of their work. The development of such a document is a multi-step process: first, a detailed analysis grid was created, listing the implications of AI in healthcare—and cross-indexing them with the various responsibilities of the regulatory colleges and other relevant regulatory bodies.

Then, building upon this grid, a survey was conducted in the spring of 2021. The purpose of this survey was to identify the issues that the representatives of the regulatory colleges considered most important to address. Specifically, the idea was to get a better understanding of what were the most pressing issues that were raised by their members with respect to the use of AI in healthcare. It also sought their views on the actions that should be taken by regulatory colleges or other authorities to address these issues. To this end, a list of measures was proposed in the survey, and respondents were invited to comment and complete the grid. Overall, 25 regulatory colleges and related health and social services' organizations were consulted[27].

One finding that emerged from the survey is that, according to a significant majority of respondents, healthcare and human relations professionals already use AIS in their practice[28]. However, according to respondents, regulatory colleges seem unsure of how to help their members navigate this technological shift. Most respondents indicated that they have not yet planned any actions to address AI-related issues, while the remainder of respondents were either considering resorting to regulation, creating guides or guidelines or providing training[29].

The issues identified in this survey are detailed in the Appendix[30]. They can be summarized into four high-level priorities:

PRIORITY 1

PROFESSIONAL TRAINING

This includes both the initial education that leads to a license to practice and continuing education. While the former generally involves higher education institutions, the latter falls more directly under the purview of regulatory colleges.

PRIORITY 2

PROTECTION OF PERSONAL INFORMATION

This priority is closely related to the ethical obligations of professionals regarding privacy and the rights of patients regarding their medical records. Regulatory colleges have oversight responsibilities over these matters.

PRIORITY 3

QUALITY AND SAFETY OF PROFESSIONAL PRACTICE

This priority is also linked to existing ethical obligations that apply to professionals. Again, regulatory colleges are responsible for ensuring that professionals comply with these obligations.

PRIORITY 4

INTERVENTION POWERS OF REGULATORY COLLEGES

Regulatory colleges are concerned about potential obstacles that may arise regarding their responsibilities concerning AIS. They mentioned, among other things, issues of explainability, intellectual property, **as well as** issues related to the inter-jurisdictional context in which AIS are used.

SECTION 3

PROPOSING PRINCIPLES: PROTOTYPE FOR A CODE OF ETHICS

Once the process of consultation with the regulatory colleges was complete, the team became interested in trying to imagine what a code of ethics for health and social services professionals would look like. The idea was to propose a "prototype" of such a code, that would address the issues discussed in the consultation process.

In French, the definition of the word prototype is a "first iteration […] directed at experimentation[31]." That is what this prototype is. It consists of 10 principles formulated in a way that resembles the provisions of the codes of ethics to which health professionals are bound. As a first iteration, the prototype is not intended to be bluntly copied into laws or regulations. It is meant to stimulate reflection and discussion.

For some of the proposed statements or principles of this prototype, regulatory colleges may conclude that existing provisions already effectively address the issue at hand. Then, there would be no need to add regulation, as redundancy and duplication should be avoided. In other cases, the integration of some principles might appear premature, given certain uncertainty regarding the impacts of AI on professional practice. In these cases, caution is certainly warranted. It is not desirable to rush to introduce ill-advised rules that would be useless at best, and that would risk stifling innovation and depriving society of the benefits of AI[32]. One way to avoid ill-advised rules, and engage with public concerns about AI, would be to involve citizens from different walks of life in the process leading to the adoption of a regulatory framework. The co-creation process that led to the development of the Montreal Declaration on AI could serve as an inspiration.

However, doing nothing out of an abundance of caution is not desirable either. A sizable amount of work has already been done on both the use of AI by professionals[33] and the use of AI in healthcare. And there are a number of existing principles that healthcare and social services professionals should follow. Perhaps it is time to take the next step and start thinking about how prescriptive norms should be formulated.

That is the purpose of this prototype. It is intended to help regulatory colleges think about how to address issues related to the use of AI by health and social services professionals. The principles outlined below can be operationalized through continuing education, guidelines, or ultimately through regulatory or legislative means. While the target audience of this document is regulatory colleges, AI developers and deployers may also find this prototype useful, as it provides clear and concise guidance on the obligations to which professionals are bound. This could ultimately help to promote a degree of technological coherence.

The prototype's principles, as presented below, build on existing ethical rules. Each principle is accompanied by a few paragraphs that explain the principle and analyze the relevant issues surrounding it. Note that the order in which the principles are presented is informed by the results of the survey—to the extent possible, the principles presented first are those related to the issues that regulatory colleges considered most pressing.

PRINCIPLE 1

The professional must ensure that he is adequately trained in AIS available in his discipline, in particular regarding the possibilities and limitations of those he uses in his practice.

ANALYSIS Like many other observers[34], Quebec's regulatory colleges have stressed that the successful integration of AI into the healthcare system depends on adequate training of health professionals.

For professionals, it is an ethical obligation to have an adequate level of training and to develop, perfect and update their knowledge[35]. Professionals who are using AIS should understand the capabilities and limitations of these systems—without necessarily understanding all the intricacies of how the algorithm works[36]. They should be able to provide sufficiently detailed information to obtain informed consent from the patient[37]. They should also understand well enough how AIS work to exercise professional judgment in selecting the AIS to be used and in interpreting the results generated by the chosen AIS. Finally, they should be aware of the risks of "judgment atrophy," a phenomenon of blind trust that can lead to overreliance (without sufficient critical thinking) on the AIS and to a deskilling effect of professionals in the long run.[38]

The responsibility of training professionals with respect to AI lies not only with the regulatory colleges, but also with the academic institutions that provide the initial education leading to licensure. Regulatory colleges can help initiate and implement changes at the academic level by working with relevant stakeholders through the education committees on which they sit alongside education sector representatives[39].

As to post-licensure training, regulatory colleges can, of course, play a significant role given their responsibilities related to continuing education. Typically, their role is to organize training activities that meet the needs of their members and to define and implement the regulatory framework that governs mandatory continuing education[40]. They are in a good position to steer the content of training activities towards topics that are important for public protection. The integration of AIS into clinical practice is one of these important topics. It is especially relevant for professionals who were not exposed to this type of training during their initial training at the university level; yet, considering the fast-changing pace of AI developments, there will potentially be a need to adapt AI training programs on a regular basis.

See what the Montréal Declaration has to say regarding explainability[41].

PRINCIPLE 2

When collecting personal information about a patient for immediate or future use in an AIS, the professional must give him the information necessary to exercise his rights and respect his choices in this regard.

ANALYSIS As things currently stand, the collection of health information is not subject to specific ethical regulations. With respect to personal information, codes of ethics are mainly concerned with the rights of access and correction[42]. However, professionals are bound by privacy protection laws. In both the public and private sectors, the applicable laws provide for information obligations when personal data is collected[43]. Among other things, data subjects must be informed of the name of the organization on whose behalf the information is being collected, the purposes for which the information is being collected, the methods used, the mandatory or optional nature of the request, and the consequences of refusing to provide the information. Patients should also be informed of their right to access and correct information pertaining to them.

These transparency requirements are meant to give people agency over the way their personal information is processed. It allows them to decide whether they agree with the purpose for which the information is collected. For instance, a patient could object to the use of his or her data by a particular company, for certain specific research purposes, or for any profit-making purpose—regardless of the fact that the data is anonymized[44].

It's worth noting that in Quebec, health and social service professionals should be submitted to a new legal framework that will apply to the public sector and to most of the private sector[45]. This new framework, that would be put in place with the adoption of Bill 3, the *Act respecting health and social services information and amending various legislative provisions,*[46] appears to be less demanding than existing laws of general application, particularly with respect to disclosure requirements. Under this new piece of legislation, it would no longer be necessary to inform the patient of the obligatory/optional nature of the collection nor will it be necessary to inform the patient of the consequences of refusing to provide the information[47]. However, the bill provides that a patient's refusal to consent to the processing of their health information—or a patient's decision to restrict access to their health information—cannot result in a denial of services[48].

In conclusion, this second principle aims to ensure that whenever a professional collects patients' personal information to train an AIS, the patient is informed about it and can exercise his rights in this regard, notably, the right to object to the collection, without being denied access to service. It should be noted, however, that in some cases, the use of anonymized data without the patient's consent is permitted by the law[49].

See what the Montreal Declaration has to say regarding the control an individual should have over their data[50].

PRINCIPLE 3

The professional must ensure that the personal information he collects while he develops or uses an AIS is kept confidential and, when required, destroyed or anonymized following best practices.

ANALYSIS It goes without saying that professionals have an obligation to ensure the confidentiality of the information they collect in the course of their practice. This obligation arises from both the duty of professional secrecy[51] and the specific rules that apply to records created in the course of professional practice and the provision of health care services[52].

Relatedly, regulatory colleges regulations provide that destruction of patient health information can only occur after several years, when it can be reasonably expected that the information is no longer useful[53]. The emphasis here is on preservation rather than destruction. However, there is a shift occurring. In Quebec, the new personal information laws for the public and private sector[54] and Bill 3[55] mandate the destruction of personal information.

These laws also provide that data anonymization can be an alternative option to destruction. From a legal point of view, anonymization is a novelty. The Quebec legislature proposes the following definition for it: information is anonymized when "if it is, at all times, reasonably foreseeable in the circumstances that it irreversibly no longer allows the person concerned to be identified, even indirectly"[56]. This new concept is clearly aimed at increasing the value of personal information while minimizing, if not eliminating, the risks to privacy[57].

Under the general regime, anonymization may replace destruction if justified by "public interest purposes"[58] or "serious and legitimate purposes"[59]. In contrast, Bill 3 does not seem to require public interest justification to replace the destruction of personal information by its anonymization. When anonymized, the data would not qualified anymore as "health and social services information" under the law, since it would no longer allows the identification of the individual, directly or indirectly[60], It may mean that that anonymized data can be reused without the patient's consent.

In conclusion, this third principle aims to integrate various concepts related to the "data lifecycle" into one general obligation. To avoid cybersecurity issues[61], regulatory colleges should consider providing more explicit guidance to ensure that their members follow best practices regarding the collection and storage of personal health information throughout its lifecycle. This could be done either through guides, guidelines or regulations[62].

See what the Montréal Declaration has to say regarding data confidentiality[63].

PRINCIPLE 4

The professional must avoid using an AIS at the expense of a relationship of mutual trust with the patient. To that end, he must respect the patient's decision to refuse the use of an AIS and propose a valid alternative given the resources available.

ANALYSIS The goal of this principle is to affirm explicitly that AIS should not undermine the relationship of trust between patients and healthcare professionals and should be seen primarily as a complement or support to clinical practice[64]. In a sense, this principle derives from one of the key foundations of professionalism, namely the personal relationship and the trust that should be established between the professional and the patient[65]. Trust between professionals and members of the public is one of the key factors to be considered in determining whether a profession needs to be regulated by a regulatory college[66]. Codes of ethics generally provide general obligation regarding relationships of mutual trust. For instance, the Code of Ethics of Physicians[67]:

> **"The physician must seek to establish and maintain a relationship of mutual trust with the patient and must refrain from practicing his profession in an impersonal manner."**

This fourth principle can be linked to certain rights granted to patients under the *Act respecting health services and social services*[68], including the right "to receive, with continuity and in a personalized and safe manner, health services and social services which are scientifically, humanly and socially appropriate"[69]. It is also strengthened by new provisions recently proposed. For example, Bill 3[70] provides that a patient's right to services cannot be affected by a decision to opt out of the use of his or her personal information. Such a provision can help foster trust between patients and professionals. In addition, the forthcoming right to "in-person services" in the context of telemedicine[71] suggests that teleconsultation services should not be imposed on users, allowing them to request face-to-face services, subject to the usual institutional limits[72]. Building on this new provision, it could be considered that the patient has the right to not be forced to receive services through AI if this results in being deprived of direct contact with a professional.

In conclusion, this fourth principle aims to ensure AIS do not hinder trust between patients and professionals. Notably, it requires that professionals offer a valid alternative to the use of AI in healthcare, within the limits of what is possible under the circumstances.

See what the Montréal Declaration has to say regarding the importance of patient-caregiver relationships[73].

PRINCIPLE 5

The professional must refrain from using AIS that have not been licensed or certified, or that are insufficiently tested on the general population or on certain groups of people, except within the context of a research project subjected to adequate ethical oversight.

ANALYSIS Codes of ethics in the health care sector often require professionals to adhere to generally accepted scientific standards and principles in their field[74] and to refrain from using methods or treatments that have not been adequately tested, except in the context of research projects[75]. In the context of AI, such provisions could help to reduce the risk of errors or malfunctions that could have a negative impact on the general population. They could also help mitigate the risks of inadequate data or biased algorithms that could have stigmatizing effects on marginalized groups and lead to situations of unlawful discrimination[76].

In applying existing provisions on scientific standards to the context of AI, it may be useful to include a requirement that AIS be approved or certified by competent authorities. This could include mandatory approval processes similar to those used by Health Canada for medical devices[77]. Certification processes, which are not required by law but are recognized as a guarantee of safety and effectiveness, could also be considered. For AIS that are not subject to certification and approval requirements, it should be the responsibility of the professional to seek relevant information in the literature to determine whether the intended use is scientifically and clinically justified.

Finally, it is worth noting that in addition to the potential inclusion of such a provision in codes of ethics, regulatory colleges also have regulatory authority over the use of devices and equipment in their members' practices[78].

See what the Montréal Declaration has to say regarding the safety and reliability requirements that AIS must meet[79].

PRINCIPLE

6

The professional must put the patient's interest first in the decision to use an AIS to provide care, regardless of his own interests or those of a third party. When he has a financial or other interests in the AIS used, he must inform the patient.

ANALYSIS Regulatory colleges must establish rules to prevent or manage conflicts of interest among their members[80]. In some cases, these rules may be of a general nature[81], while in in other cases, the rules may be specific to the relationships that professionals have with stakeholders[82]. For example, rules governing relationships between certain health care professionals and the pharmaceutical industry, as well as with manufacturers of instruments and other products related to the health care professions.

Professionals working with the AI industry are likely to face similar issues to those faced by professionals working with pharmaceutics or medical devices fabricants[83]. It might not be desirable to impose a strict ban on the participation of professionals in projects aimed at developing or commercializing AIS. However, from an ethical point of view, it is certainly necessary to regulate these relations and to impose transparency requirements. This is the aim of this principle, which affirms that the interests of the patient must always be paramount and that patients must be informed of any financial or other interests that the professional may have in relation to the AIS being used[84].

On a different note, the interest of the patient and society might also lie in reducing the cost of health care. In this regard, most codes of ethics state that professionals should charge reasonable fees for their services, and some even specify various factors to be considered, including the time spent providing services[85].

It is not certain that using an AIS will always result in efficiency and time savings. In some cases, it may even be an additional step on top of the usual clinical procedures, aimed at reducing risks or improving the quality of services, and thus not result in time savings[86]. It is also clear that the cost of acquiring and maintaining devices and equipment, including those with AIS, can be factored into fee structures[87].

In other cases, however, such efficiencies may indeed exist, for example, where the use of an AIS accelerates the completion of certain clinical tasks, such as reading x-rays or making a diagnosis. In this context, it would be appropriate to take this into account when setting fees.

See what the Montréal Declaration has to say regarding the primary goal of individual health, social and economic well-being[88].

PRINCIPLE 7

The professional must provide, in a manner proportionate to the level of risk, the information necessary to obtain the free and informed consent of the patient receiving care from an AIS. Notably, he must inform the patient of the result generated by the AIS, its interpretation and, when applicable, of any significant problems that have arisen during its use.

ANALYSIS This principle is directly inspired by a provision introduced in the French Public Health Code in 2021[89], which aims to ensure that patients are provided with sufficient information to give their free and informed consent to the use of an AIS and the interpretation of the results obtained.

This is not a new obligation, of course, as it derives from fundamental rights such as the right to security, integrity, and liberty, which are enshrined in the *Quebec Charter*[90]. It's also enshrined in the Civil code of Quebec[91], the *Health and Social Services Act*[92], not to mention professional codes of ethics[93].

In addition, Bill 3[94] on health information and the general laws on the protection of personal information[95] require that individuals be informed when their personal information is used to make a decision based solely on automated processing. In addition, at the federal level, a bill that would create the first law specifically dealing with artificial intelligence also includes requirements for information to be provided to the public about "high-impact" AIS[96].

It should be noted that this principle would not only apply to situations where a clinical decision is based solely on the use of AIS, which should not generally be the case as professionals are usually expected to interpret the results and exercise clinical judgment accordingly.

The principle is written to allow for a degree of flexibility in the duty to inform, with the intensity of the information provided depending on the risks involved, amongst other considerations. This reflects the general practice of informing patients about the risks associated with various treatments, whether surgical, pharmacological or otherwise[97]. Thus, the lower the risks, the less detailed information would need to be provided, and vice versa.

Finally, it should be considered that there may also be an obligation to inform the patient in the case of certain critical clinical decisions in which a professional significantly deviates from a recommendation resulting from the use of an AIS. Similarly, an obligation to inform the patient should be considered in cases of breaches of confidentiality where there is a risk of serious harm, as provided for in Bill 3[98] and the general laws on the protection of personal information[99].

See what the Montréal Declaration has to say regarding the right of a person affected by a decision or other action resulting from the use of AIS to be informed of it and to demand a review by a human[100].

PRINCIPLE

8

The professional who develops or uses an AIS in his practice must make available to the competent authorities all information relevant to the assessment of its safety and effectiveness. He must provide objective information in any public intervention he makes regarding the AIS and shall not be party to any agreement that limits his obligations in this respect.

ANALYSIS The purpose of this principle is to establish an obligation to report problematic situations to the relevant authorities. This is part of a broader effort to ensure the assessment of the safety and effectiveness of AIS throughout their lifecycle. This obligation is particularly important given the ability of certain forms of AI (such as machine learning) to evolve autonomously without being able to provide an intelligible explanation of the motives that guide their decision-making process.

In the same spirit, and taking into account that offering services based on AI could lead to false or exaggerated claims or even misinformation[101], this principle aims at ensuring that professionals publicly communicate objective information about the limitations and capabilities of AIS. It is worth noting that public communication by professionals, especially in advertising, is already subject to professional regulation[102]. The relevant provisions stipulate that professionals may not make false, misleading, or incomplete statements about their level of competence, the quality of the services they provide, etc.

Finally, this principle also seeks to make it illegal for professionals to enter into commercial agreements that would prevent them from sharing the information needed to assess the safety and effectiveness of AIS, or that would encourage them to disseminate inaccurate information.

See what the Montréal Declaration has to say regarding the reporting of errors and flaws in AIS to public authorities and public access to this information[103].

PRINCIPLE 9

The professional must not elude or attempt to elude professional liability for the consequences that may result from his use of an AIS.

ANALYSIS Much has been written about liability issues resulting from the use of AI in healthcare. When multiple parties are responsible for causing harm—consider a situation involving a healthcare professional, the institution in which he practices and the developers and manufacturers of the AIS he used—how should liability be apportioned?

It is well established that health professionals, regardless of the organizational context in which they practice[104], cannot elude their responsibility for their professional activities[105]. However, this does not mean that professionals should be held liable for the consequences of any incident or accident that may occur in the course of their activities, especially when the professional has not committed any fault and that the harm results from a problem in the AIS[106].

In determining how the liability should be apportioned, several factors must be considered: the importance of not leaving a patient without recourse, the desire to encourage optimal and efficient use of AIS by professionals, the possibility that, as it evolves, the AIS produces results that were not initially foreseen, etc.[107].

In order to facilitate access to compensation for victims of harm resulting from the use of an AIS in healthcare[108], regulatory colleges could consider amending their professional liability insurance rules. This should be done in accordance with the limits of their prerogatives.

In conclusion, this 9th principle does not propose a specific liability regime for AIS, but simply reaffirms that professionals are responsible for their professional activities and should not invoke the autonomous nature of AIS to evade their liability[109]. Professionals must remain responsible for some specific decisions, namely the choice of the AIS they use, and the interpretation of the results generated by these systems.

See what the Montréal Declaration has to say regarding the continued responsibility of humans for harm resulting from the use of AIS[110].

PRINCIPLE 10

The professional must, within the limits of his ability and without prejudice to patients' rights, contribute to the development of AIS that are safe, effective, sustainable, and respectful of human diversity in his area of practice. Notably, he should facilitate access to the data he collects and participate in research activities.

ANALYSIS Starting from the premise that the use of AI in healthcare could be beneficial to patients and society—if responsible governance mechanisms are in place—it is worth considering the possibility of subjecting healthcare professionals to an obligation to contribute to its development.

One notable contribution they could make would be to allow AI developers access to the information collected in the course of their practice so that AIS can be trained on this data. The cooperation of health institutions would also be needed, given that the platforms used to collect and store the data significantly impacts how the data can be processed. Record-keeping systems that meet interoperability requirements should be prioritized as it enables information sharing between comparable systems, making the training of AIS easier and more effective[111].

Regulatory colleges have specific powers that would allow them to set standards with respect to interoperability[112]. Moreover, the legislator or certain government agencies could also adopt a regulatory framework to promote interoperability at a broader level—Quebec actually envisages such regulation in Bill 3[113] concerning health information.

In addition to interoperability standards, regulatory colleges could also intervene in other areas, like clinical research projects. While ethical oversight of research is primarily the responsibility of academic institutions and funding agencies[114], several regulatory colleges have introduced provisions in this regard in their codes of ethics[115], as healthcare professionals in various disciplines are often involved in clinical research projects.

In conclusion, this 10th principle proposes to establish an obligation for professionals to contribute to the development of AIS that are safe, effective, environmentally sustainable, and respectful of human diversity[116]. This principle complements existing provisions under which professionals are responsible for advancing knowledge and promoting the quality and accessibility of healthcare services related to their discipline[117]. In practice, this principle would include an obligation to make the data collected by professionals available to AI developers—although it should be acknowledged that professionals are not always fully in control of the technological choices related to their practice environment and that patient's rights must always take precedence when it comes to data sharing.

See what the Montréal Declaration has to say regarding the importance of ensuring the contribution of all relevant actors to the development of AIS that benefit society as a whole[118].

CONCLUSION

Two important observations emerge from this project. The first one is that regulatory colleges are concerned with their members' use of AI in clinical contexts. The second is that they are in a somewhat good position to do something about it. Indeed, through professional regulation and training activities, regulatory colleges can play a significant role in ensuring that rules and best practices related to AI in healthcare are adequately integrated into clinical settings.

The challenge, however, is to identify the substance of these rules, or at least the broad principles underpinning them. This is particularly challenging given that it is not yet entirely clear how future AI developments will be integrated in healthcare. Nevertheless, this prototypical code of ethics represents an attempt, albeit an imperfect and incomplete one, to imagine what these rules could look like. The main purpose of the prototype is not necessarily to be translated into laws or regulations—a proper assessment of the effectiveness of existing provisions should be conducted to determine whether this is warranted—but rather to provide relevant guidance that can be shared with professionals either through continuing education, guides and guidelines or other types of training activities.

Regulatory colleges have demonstrated a genuine willingness to support their members in navigating the introduction of AI in healthcare, a technological shift likely to disrupt the way the healthcare system works both in Quebec and abroad. The next step is to coordinate the efforts to ensure that each professional discipline adheres to a set of rules and principles aimed at maximizing the benefits of using AI in the healthcare system while minimizing the negative consequences that may result.

NOTES

1 WORLD HEALTH ORGANIZATION (hereinafter: "WHO"), *Ethics and governance of artificial intelligence for health: WHO guidance*, 2021, pp. 2-3, online: https://www.who.int/publications/i/item/9789240029200 (accessed March 4, 2022).

2 UNIVERSITÉ DE MONTRÉAL, *Montréal Declaration for a Responsible Development of Artificial Intelligence* (hereinafter: "Montreal Declaration"), online: https://www.montrealdeclaration-responsibleai.com/ (accessed July 3, 2022).

3 Catherine RÉGIS & Colleen M. FLOOD, "AI and Health Law", in Florian Martin-Bariteau & Teresa Scassa, eds, *Artificial Intelligence and the Law in Canada*, Toronto, LexisNexis Canada, 2021, pp. 4-6.

4 R.S.C 1985, c. F-27.

5 SOR/98-282.

6 HEALTH CANADA, *Guidance Document: Software as a Medical Device: Definition and Classification*, adoption date: 2019/10/03, effective date: 2019/12/18, online: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance-document.html (accessed March 15, 2023).

7 See discussions held on the subject at this event: CENTRE FOR RESEARCH IN LAW, TECHNOLOGY AND SOCIETY, *The Regulation of Medical Devices with Artificial Intelligence*, University of Ottawa, November 8, 2021, recording available online: https://techlaw.uottawa.ca/aisociety/events/regulating-medical-devices?1919= (accessed on January 10, 2023).

8 See the current *Personal Information Protection and Electronic Documents Act*, S.C. 2000, c. 5.

9 *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR c. A-2.1; *Act respecting the protection of personal information in the private sector*, CQLR, c. P-39.1.

10 *An Act to modernize legislative provisions as regards the protection of personal information*, S.Q., 2022, c. 25 (hereinafter "Bill 25").

11 *An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts*, 1st Session, 44th Parliament, Bill C-27 (First Reading), s. 39 (11). A regulation should eventually define what a "high-impact system" is: s. 39 (s. 5).

12 *Id. at* Part 3, s. 39 (ss. 5, 7, 8, 9, 11, 12, 14, 17, 36[b])

13 This is at least what can be anticipated if one considers the European Union approach in this matter, where it seems that medical devices will be categorized as "high risk": *Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts*, Brussels, 21.4.2021, COM (2021) 206 final, 2021/0106 (COD), online: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52021PC0206&from=EN (accessed July 6, 2021), part 1.2, art. 6 par. 1 and Annex II par. 11.

14 See the *Act respecting health services and social services*, R.R.S.Q., c. S-4.2 (hereinafter: "*A.H.S.S.S.*")

15 *Health Insurance Act*, CQLR, c. A-29.

16 *Hospital Insurance Act*, CQLR, c. A-28.

17 *Act respecting prescription drug insurance*, R.S.Q., c. A-29.0

18 See, for example, what currently stems from the *Act respecting the sharing of certain health information*, R.R.S.Q., c. P-9.0001; ss. 17 to 28 H.S.*A.* See also the subsequent explanations regarding the proposed new legal framework for health information.

19 *Act respecting the Institut national d'excellence en santé et en services sociaux*, CQLR c. I-13.03.

20 *Constitution Act, 1867*, 30 & 31 Vict, U.K., c. 3, s. 92 para. 13. In this regard, see, among others: *Law Society of British Columbia* v. *Mangat*, 2001 SCC 67; *Lafferty* v. *Lincoln*, (1907) 38 S.C.R. 620.

21 See the list of currently constituted professional orders in Schedule I of the *Professional Code*, R.R.S.Q., c. C-26 (hereinafter: "P.C.").

22 See, for example, the supervisory role of the Office des professions du Québec, a government agency, and the review and approbation powers of the Office and the Quebec Government related to regulations adopted by professional orders: ss. 3 to 16.2 and 95 to 95.2 *C.P.*

23 Art. 87 to 95.4 *C.P.*

24 See in particular sections 109 to 161.1 *C.P.* On the public order nature of the ethical obligations arising from the regulations of the professional orders, see in particular: *Gestion Philippe Girard inc.* v. *Clinique de réhabilitation prosthodontique de Québec inc.* 2022 QCCA 1146; *Mirarchi* v. *Lussier*, 2007 QCCA 284; *Ordre des diététistes du Québec (OPDQ)* v. *Centre hospitalier de l'Université Montréal (CHUM)*, 2022 QCCS 1795.

25 S. 94 par. o) *C.P.*

26 C. RÉGIS & C. M. FLOOD, supra note 3, p. 6.

27 In total, the 25 professional orders and partner organization respondents could be categorized as follows: 15 respondents from physical health professional orders, 4 from mental health and human relations professional orders, and 4 from professional orders whose members may practice in any of these sectors; 1 from a partner organization.

28 For the question, "Do members of your professional order currently use AIS or is it plausible that they will use it in the future?" the raw data for the choices expressed are Yes: 21; No: 1; Don't know: 1; Not applicable (if not answering for a professional order): 2. In contrast, see one of the findings of this study of professionals in 2020-2021, indicating that one third of them do not know if their company or organization uses AI-based tools: Nathalie DE MARCELLIS-WARIN, Christophe MONDIN, *Les pratiques numériques des professionnels au Québec, État des lieux et pistes de réflexion pour accompagner le virage numérique*, Report prepared by the International Observatory on the Societal Impacts of AI and Digital Technology (OBVIA) in collaboration with the Centre interuniversitaire de recherche en analyse des organisations (CIRANO) as part of a research project proposed by the Quebec Interprofessional Council (hereinafter: "CIQ"), 2021, p. 45, online: https://www.cirano.qc.ca/files/publications/2021RP-14.pdf (accessed September 19, 2022).

29 For the question "What interventions does your order (or other organization) plan to undertake to supervise or support professionals in the use of AIS training: 10; None for the time being: 14; Not applicable (if not answering for a professional order): 1; Other: 3

30 For this component, the raw data for the choices expressed are as follows: Training (initial and continuing), admission to practise and maintenance of competencies: 15; Confidentiality, professional secrecy, access to personal information: 14; Jurisdiction of professional orders over their members and non-members (e.g., inter-jurisdictional telepractice): 13; Quality (safety) of the professional act: 11; Consent and free choice: 6; Quality of the professional relationship: 6; Integrity and conflicts of interest, professional independence: 5; Maintenance of records and offices (instrumentation, equipment, etc.): 3; Supervision of professional research activities: 1; Relations with the professional order, colleagues and other professionals: 1; Professional liability insurance and indemnification: 0; Advertising and public communications: 0; Financial aspects, impact on the pricing (fees) of professional services: 0; Other: 0.

31 See this definition of "prototype" in the *Larousse* online dictionary: https://www.larousse.fr/dictionnaires/francais/prototype/64610 (accessed on November 15, 2021; translation from French): "The first constructed copy of a mechanical assembly, device, or machine, which is intended for experimental testing of its qualities in order to prepare for mass production."

32 WHO, supra, note 1, p. 106

33 In addition to the results of the approach described in this text, see also what emerges from the following work, which concerns all Quebec professionals, including those practising outside the health and human relations sector: N. DE MARCELLIS-WARIN, C. MONDIN, supra, note 28, p. 58; CIQ, *Dans le système professionnel, Pistes de réflexion pour un encadrement de l'intelligence artificielle*, 2021, online: https://cdn.ca.yapla.com/company/ CPYY3Q7Y2h 7Qix1QmII4X3Rf/asset/ files/8954_PisteReflexionEncadrement-IA-DsSystProfess_V3-A%20(1). pdf (accessed November 19, 2022); Jacqueline CORBETT, Chris Emmanuel TCHATCHOUANG WANKO, *Les enjeux transversaux au déploiement et à l'utilisation de l'AI au sein du système professionnel québécois*, Report prepared by the Observatoire international sur les impacts sociétaux de l'AI et du numérique (OBVIA) for the CIQ, 2022, online: https://www.docdroid.com/XZZVDuD/rapport-ciq-enjeux-de-ploiement-utilisation-ia-systeme-professionnel-quebecois-2022-pdf (accessed November 19, 2022).

34 See for example what is underlined by a panel of experts mandated by the European Parliament: PANEL FOR THE FUTURE OF SCIENCE AND TECHNOLOGY (STOA), *Artificial intelligence in Health care, Applications, risks, and ethical and societal impacts*, European Parliamentary Research Service, June 2022, p. 17-19, online: https://www.europarl.europa.eu/ RegData/etudes/STUD/2022/729512/ EPRS_STU(2022)729512_EN.pdf (consulted on 14 November 2022). See also: WHO, supra, note 1, p. 71; J. CORBETT, C. E. TCHATCHOUANG WANKO, supra, note 33, p. 33.

35 For example, see section 44 of the *Code of Ethics of Physicians*, CQLR, c. M-9, r. 17.

36 See in particular the following statement of par. III of Article L. 4001-3 of the French *Public Health Code*, as introduced by *Law n° 20211017 of 2 August 2021 on bioethics* (translation from French): "The designers of an algorithmic treatment [...] shall ensure that its operation is explicable for users". See also the WHO's analysis of this issue, particularly with regard to the "black box" phenomenon: supra, note 1, pp. 45-49 and 106-108. See also: STOA, supra note 34, at 22-23; CIQ, supra note 33, at 23.

37 For this, see principle 7.

38 On this subject, see in particular the remarks made in this conference: Catherine RÉGIS, Conférence N.5, Consortium Santé Numérique, Symposium international Innovation responsable en santé numérique January 29 and 30, 2020, February 13, 2020, online: https://www. youtube. com/watch?v=xgyupgb5OYQ (consulté 20 novembre 2022). See also the concerns expressed here: CIQ, supra, note 33, pp. 20-21. See also the interesting work of Professor Mireille Hildebrandt on this topic, for example: Mireille Hildebrandt, "Law as Computation in the Era of Artificial Legal Intelligence", 68 (1) (2018) U. of Toronto Law Jour. P.12-35.

39 These committees are generally constituted in accordance with section 184 par. 2 *C.P.* See for example the *Regulation respecting the committees on training of the Ordre des infirmières et infirmiers du Québec*, CQLR, c. I-8, r. 11

40 S. 62.0.1 (6) and 94 (o) C.P.

41 See the following principle and statements: "5. Democratic Participation principle: 1. AIS processes that make decisions affecting a person's life, quality of life, or reputation must be intelligible to their creators; 2. The decisions made by AIS affecting a person's life, quality of life, or reputation should always be justifiable in a language that is understood by the people who use them or who are subjected to the consequences of their use. Justification consists in making transparent the most important factors and parameters shaping the decision, and should take the same form as the justification we would demand of a human making the same kind of decision; 7. We must at all times be able to verify that AIS are doing what they were programed for and what they are used for."

42 See s. 87 par. 4 *C.C.* which, with respect to the mandatory content of codes of ethics, refers only to the issues of access, rectification and delivery of documents and not specifically to the issue of collection of information. This does not preclude the addition of requirements on this subject, either in the code of ethics or in a regulation on record keeping: s. 91 *C.C.P.*

43 S. 65 *A.I.A.* and S. 8 *A.P.R.S.P.* These provisions will be amended in September 2023 following the adoption of Bill 25. On privacy and data security issues related to AI, see also: WHO, supra, note 1, at 35-41; STOA, supra, note 34, at 22-23.

44 See in particular sections 6 to 8 of Bill 3. See also: WHO, supra, note 1, at 39-40.

45 The purpose of Bill 3 is to regulate health information for public and private institutions, for the private practices of professionals and for various other settings, repealing or setting aside, as the case may be, the provisions of the following statutes in this regard: ss. 17 to 28 *A.H.S.S.S.; Act respecting the sharing of certain health information*, supra, note 18; *A.A.D.*; *A.P.P.I.P.S.*

46 *Act respecting health and social services information and amending various legislative provisions*, 1st session, 43rd Parliament (Québec), 2022 (introduction; hereinafter "Bill 3"); replaces Bill 19 introduced in November 2021, but which was not adopted at the end of the parliamentary session: *An Act respecting health and social services information and amending various legislative provisions*, introduction, 2nd session, 42nd Parliament (Quebec), 2021 (introduction).

47 Bill 3, s. 14.

48 *Id.* at 10.

49 See explanation of Principle 3 on use of anonymized data without patient consent.

50 See the following principle and statement: "3. Protection of privacy and Intimacy principle: 6. Every person must be able to exercise extensive control over their personal data, especially when it comes to its collection, use, and dissemination. Access to AIS and digital services by individuals must not be made conditional on their abandoning control or ownership of their personal data."

51 *Charter of Human Rights and Freedoms*, CQLR, c. C-12, s. 9; s. 60.4 and 87 par. 3 *C.P.* See also provisions in codes of ethics, such as the following: *Code of Ethics of the members of the Ordre professionnel des travailleurs sociaux et des thérapeutes conjugaux et familiaux du Québec*, CQLR, c. C-26, r. 286.1, art. 39 à 46.

52 See for example section 11 of the *Regulation respecting the records, places of practice and cessation of practice of a physician*, CQLR, c. M-9, r. 20.3. See also s. 19 *A.H.S.S.S.*

53 *Id. See for example* section 12.

54 See, in particular, sections 53 and 73 of the *A.A.D.* and sections 10 and 23 of *A.P.P.I.P.S.*, taking into account the amendments to be introduced by Bill 25 as of September 2023.

55 See in particular ss. 5 and 103.

56 According to the definition proposed in section 103 of Bill 3, similar to those of Bill 25, introduced as of September 2023 in sections 73 of *A.A.D* and 23 of *A.P.P.I.S.P.*

57 See, for example, WHO, supra note 1 at 35-41. An attempt to re-identify de-identified or anonymized information could result in a penal offence: Bill 3, s. 149; s. 159(2) *A.A.D.* and s. 91(3) *A.P.P.I.P.S.*, as amended by Bill 25 as of September 2023.

58 S. 73 *A.A.D*

59 S. 23 *A.P.P.I.P.S.*

60 See the definition of health information in s. 2 of Bill 3, in contrast to the definition of anonymization in s. 103.

61 See the finding of this study conducted in 2020-2021 among Quebec professionals indicating that they "have little or no awareness of the issue of cybersecurity": N. DE MARCELLIS-WARIN, C. MONDIN, supra, note 28, p. 58.

62 Provisions in this regard could be included in the code of ethics or in a regulation relating to the records kept by professionals: s. 87 and 91 *C.P.*

63 See the following principles and statements: "3. Protection of privacy and intimacy principle: 5. DAAS must guarantee data confidentiality and personal profile anonymity; 8. Prudence principle: 4. The development of AIS must preempt the risks of user data misuse and protect the integrity and confidentiality of personal data."

64 See what the WHO says on this issue: supra, note 1, at 46-48.

65 See what the WHO says on this issue: supra, note 1, at 46-48.

66 On this issue, see: CIQ, supra, note 33, at 25-25.

67 Supra, note 35, s. 18.

68 Supra, note 14.

69 S. 5 *A.H.S.S.S.*

70 S. 10.

71 See section 6 of *A.H.S.S.S.*,as it will be amended following *the* coming into force of the new legislation: *An Act to increase the supply of primary care services and to improve the management of that supply*, S.Q., 2022, c. 16, s. 20. The first paragraph of this section will henceforth read as follows: "Every person is entitled to choose the professional or the institution from whom or which he wishes to receive health services or social services. The person is also entitled to have those services provided to him in person.".

72 See section 13 *A.H.S.S.S.*

73 See the following principles and statements: "4. Solidarity principle: 3. AIS should not be implemented to replace people in duties that require quality human relationships, but should be developed to facilitate these relationships; 4. Health care systems that use AIS must take into consideration the importance of a patient's relationships with family and health care staff. 9. Responsibility principle: 2. In all areas where a decision that affects a person's life, quality of life, or reputation must be made, where time and circumstance permit, the final decision must be taken by a human being and that decision should be free and informed."

74 For example, section 5 of the *Code of Ethics of Psychologists*, CQLR, c. C-26, r. 212.

75 For example, section 48 of the *Code of Ethics for Physicians*, supra, note 35.

76 See, for example, WHO, supra note 1 at 29-30, 54-57; STOA, supra note 34 at 15-17, 20-22.

77 See the processes established by the *Food and Drugs Act* and the *Medical Devices Regulations*, supra, notes 4, 5 and 6.

78 S. 91 *C.P.*

79 See the following principles and statements: "6. Equity principle: 1. AIS must be designed and trained so as notto create, reinforce, or reproduce discrimination based on — among other things — social, sexual, ethnic, cultural, or religious differences. 8. Prudence principle: 3. AIS must be designed and trained so as not to create, reinforce, or reproduce discrimination based on — among other things — social, sexual, ethnic, cultural, or religious differences."

80 S. 87 par. 2. *C.P.*

81 For example: *Code of Ethics of Physicians*, supra, note 35, s. 63.

82 For example: *Id. at* 73, 73.1, 76, 77, 79

83 See what the WHO says about this: supra, note 1, pp. 61-64.

84 In this same perspective, see for example: *Code of Ethics of Physicians*, supra, note 35, ss. 63, 73 par. 2 and 79

85 *Code of Ethics of Optometrists*, CQLR, c. O-7, r. 5.1, s. 73 par. 2.

86 On the question of the cost-benefit ratio of robot-assisted surgery, see for example: BINET A, BALLOUHEY Q, CHAUSSY Y, DE LAMBERT G, BRAÏK K, VILLEMAGNE T, BECMEUR F, FOURCADE L, LARDY H. "Current perspectives in robot-assisted surgery. *Minerva Pediatr.* 2018 Jun;70(3):308-314.

87 *Code of Ethics of Optometrists*, supra, note 85, s. 73 par. 4.

88 See the following principle and statements: "1. Well-being principle: 1. AIS must help individuals improve their living conditions, their health, and their working conditions. 3. Equity principle: 3. AIS development must produce social and economic benefits for all by reducing social inequalities and vulnerabilities."

89 Article L. 4001-3 par. I of the *Public Health Code*, as introduced by *Law no. 20211017 of 2 August 2021 on bioethics* (translation from French): "The health professional who decides to use, for an act of prevention, diagnosis or care, a medical device comprising algorithmic data processing whose learning has been carried out on the basis of massive data shall ensure that the person concerned has been informed and that they are, where appropriate, warned of the resulting interpretation."

90 *Charter of Human Rights and Freedoms,* supra, note 51, s. 1.

91 See sections 3, 10 to 31.

92 S. 8, 9 and 10, *A.H.S.S.S.*

93 For example, section 17 of the *Code of Ethics of Physiotherapists and Physiotherapy Technologists*, CQLR, c. C-26, r. 197.

94 S. 58.

95 See the following provisions that will be in force in September 2023: *Act respecting Access to documents held by public bodies and the Protection of personal information*, CQLR, àc. A-2.1 (hereafter: "*A.A.D.*"), s. 65.2; *Act respecting the protection of personal information in the private sector* (hereafter: "*A.P.P.I.P.S.*"), CQLR, c. P-39.1, s. 12.1. These provisions result from the adoption of Bill 25.

96 *An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts*, supra, note 9, s. 39 (11).97 See, namely: *M. G.* v. *Pinsonneault*, 2017 QCCA 607, *Ferland* v. *Ghosn*, 2008 QCCA 797.

97 S. 3 and 100 to 102.

98 S. 3 and 100 to 102.

99 S. 63.7 to 63.10 B.*A.I.* and ss. 3.5 to 3.8 B.*A.I*

100 See the following principles and statements: "5. Democratic participation principle: 8. Any person using a service should know if a decision concerning them or affecting them was made by an AIS; 9. Any user of a service employing chatbots should be able to easily identify whether they are interacting with an AIS or a real person.; 9. Responsibility principle: 2. In all areas where a decision that affects a person's life, quality of life, or reputation must be made, where time and circumstance permit, the final decision must be taken by a human being and that decision should be free and informed."

101 See the reference to "snake oil" marketing: WHO, supra, note 1, at 106.

102 See in particular: ss. 60.1 to 60.3 C.P.; *Code of Ethics of Physicians*, supra, note 35, ss. 88 to 93.3

103 See the following principles and statements: "5. Democratic participation principle: 4. The discovery of AIS operating errors, unexpected or undesirable effects, security breaches, and data leaks must imperatively be reported to the relevant public authorities, stakeholders, and those affected by the situation. 8. Prudence principle: 5. The errors and flaws discovered in AIS and SAAD should be publicly shared, on a global scale, by public institutions and businesses in sectors that pose a significant danger to personal integrity and social organization.

104 See, for example, section 187.19 *C.P.* with respect to the liability of a professional practicing within a corporation.

105 See, for example, section 11 of the *Code of Ethics for Pharmacists*, c. P-10, r. 7

106 On this subject, see in particular: WHO, supra, note 1, at 76-77; STOA, supra, note 34, at 25-27.

107 Who, Supra, note 1, at 76-80.

108 See the regulations that professional orders must adopt regarding the applicable requirements for professional liability insurance, pursuant to article 93 d) *C.P.*, such as the *Regulation respecting professional liability insurance for physicians*, CQLR, c. M-9, r. 15. A true no-fault liability regime for recourse to an AIS could probably not result from the adoption of such a regulation, but this is one direction suggested by the WHO to address the difficulties involved: supra, note 1, pp. 78-79.

109 In the same sense, see: CIQ, supra, note 33, at 21-22.

110 See the following principle and statements: "9. Responsibility principle: 1. Only human beings can be held responsible for decisions stemming from recommendations made by AIS, and the actions that proceed therefrom; 5. When damage or harm has been inflicted by an AIS, and the AIS is proven to be reliable and to have been used as intended, it is not reasonable to place blame on the people involved in its development or use."

111 WHO, supra note 1 at 87-90; STOA, supra note 34 at 27-29.

112 S. 91 *C.P.*

113 See, in particular, the criteria for the certification of technological products or services that may be established by the Minister, particularly with respect to interoperability, under section 84 of Bill 3.

114 See in particular: HUMAN SCIENCE RESEARCH COUNCIL, NATURAL SCIENCES AND ENGINEERING RESEARCH COUNCIL OF CANADA, HEALTH RESEARCH INSTITUTES OF CANADA, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans TCPS 2 (2018)*, Government of Canada, 2018, online: https://ethics.gc.ca/eng/ policy-politique_tcps2-eptc2_2018. html (accessed 5 July 2022).

115 See, for example, the *Code of Ethics for Pharmacists*, supra, note 105, ss. 87-93.

116 On the impact of AI on environmental issues, see WHO, supra, note 1, p. 64.

117 For example, sections 3.1 and 15 of the *Code of Ethics for Physicians*, supra, note 35.

118 See the following principles and statements: "6. Equity principle: 3. AIS development must produce social and economic benefits for all by reducing social inequalities and vulnerabilities. 7. Diversity inclusion principle: 3. AI development environments, whether in research or industry, must be inclusive and reflect the diversity of the individuals and groups of the society. 10. Sustainable development principle: 4. Public and private actors must support the environmentally responsible development of AIS in order to combat the waste of natural resources and produced goods, build sustainable supply chains and trade, and reduce global pollution."

APPENDIX

Excerpt from the analysis grid submitted to the professional orders in the health and human relations sector regarding their various responsibilities and the issues surrounding AI

TOPICS CORRESPONDING TO THE RESPONSIBILITIES OF PROFESSIONAL ORDERS	POTENTIAL IMPACTS AND ISSUES RELATED TO AIS IN HEALTH
Admission to practice (diploma granting access to a license, additional conditions, equivalences, specialties, etc.) **General ethical duties towards the public** (on a collective/ populational level)	Because health professionals and other professionals (e.g., engineers, lawyers) are likely to be involved both in the development and use of AI systems (AIS), it is imperative that they receive education and training quickly. The ethical obligations of health professionals generally require them to protect and promote health and well-being, and to contribute to improve the accessibility and quality of health services, on an individual and collective basis. In this context, they should be concerned about the various implications of their contributions to the development and use of AIS throughout their careers. Furthermore, it is important that training in AIS and in information technologies in general (electronic records, telemedicine, etc.) is not limited to a marginal part of the training program (e.g., a 3-hour course). This training should be integrated into various educational activities so that professionals develop the necessary skills and abilities in each area of their professional practice.
Continuing education	Ditto. The frequent, or even systematic, use of AIS instead of an unassisted clinical approach (physical examination) could lead to the loss of certain skills, thus posing risks in the event of technological failures.
Record keeping, access, rectification, etc.	One of the most important issues concerning patient records, whether electronic or not, is undoubtedly that of privacy (see the section entitled “Professional secrecy and confidentiality”). One of the first questions that arises in this context is the responsibility of the professional with respect to the data collected in the course of providing care. In a traditional context, this data remains under their control, whether or not it is shared with a healthcare organization (such as a patient’s record in a facility or clinic). If this data ends up, in one form or another, under the control of a third party, such as a manufacturer of instruments using AIS or a commercial platform offering services using AIS, how can the professionals exercise the expected control over this data in relation to their obligations and patients’ rights (access, rectification, etc.)?

In addition, the question of the need to obtain specific consent arises when the professional collects data about a patient for the purpose of (immediately or eventually) feeding one (or more) AIS, rather than solely for the purpose of providing care.

Another question that arises is to what extent should a patient be able to identify the AIS that were used in the care they received by consulting their health record? Should they be able to identify instances where the professional has deviated from the recommendations generated by an AIS, as if it were an incident?

Finally, some standardization of records and data may be desirable, particularly to ensure portability and interoperability. This includes ensuring that a patient's data can be transferred between different electronic records, and promoting the use of these data by AIS when the public interest justifies it. In this regard, it may also be necessary to consider the data contained in professional records as a "digital commons" and to explore the possibility of transforming them into "open data" to support positive developments in AI.

Professional secrecy, confidentiality and use of personal information

The risks associated with the use of AIS in terms of professional secrecy and confidentiality are not negligible, given that it is primarily patient data that powers these systems. It is conceivable to anonymize the data in order to avoid potential situations in which patients' rights could be compromised, especially when these data are transferred to third parties responsible for the development or deployment of solutions or devices involving AIS. However, anonymization processes must be carried out rigorously to minimize the possibility of re-identification.

Furthermore, the use of AIS obviously involves the use of digital platforms from which patient data can be exploited. In many cases, this data will come from electronic health records, which raise specific concerns about the protection of professional secrecy and confidentiality.

Finally, there are issues related to the control that patients should be able to maintain over their data, particularly in relation to the different potential uses of AIS. Following the usual principles of personal data protection, patients' rights of control over the various possible uses of their personal data should be respected, including the right to refuse and withdraw consent where appropriate.

Quality and safety of professional practice, adherence to generally recognized scientific standards, etc.

The ethical obligation to adhere to generally accepted standards and scientific principles should require professionals to exercise critical judgment when using AIS to ensure that these systems meet this requirement. They should avoid systematically relying on results obtained without taking into account the inherent limitations of the AIS and the specific patient situation. This also means that professionals should have sufficient information about the functioning and limitations of the AIS they are using so that they can effectively exercise critical judgment in this regard.

Furthermore, an inherent risk of using AIS based on algorithms is the reinforcement of biases and stereotypes. It is well known that the development of these algorithms requires large data sets about individuals. The use of historical data in AI learning can be problematic because it can reinforce or perpetuate existing biases. While the ultimate goal in algorithm development is "algorithmic neutrality," achieving this in practice can be challenging. Underrepresentation of certain groups of people in selected data sets can significantly affect the performance of the algorithm with respect to those groups.

The risks of marginalization, stigmatization, and potentially unlawful discrimination associated with the use of AIS are of particular concern in health care, given the potentially serious impact on individuals' health. For this reason, diversity, representation, and inclusivity are often discussed by researchers: these principles need to be taken into account in the design of AIS, as well as later in their use.

Consent, freedom of choice, etc.

Requirements for obtaining consent to treatment generally mean that it should be free and informed, based on adequate information about the benefits and risks of the proposed treatment. Where the use of an AIS is being considered and could involve significant risks, the patient should be provided with the relevant information in order to obtain his or her consent. The patient's refusal to use an AIS should not compromise their access to services.

Given that the consent requirement is an ongoing obligation and not a one-time event, should the patient also be informed about significant incidents that may occur during treatment with AIS—for example, if the professional decides to disregard the AIS's recommendations?

Finally, the requirement for consent also applies to the use that could be made of the patient's data collected in the context of the AIS (see the section on "Professional secrecy, confidentiality and use of personal information"). This may result in the need for multiple consents from the patient or an expanded approach to obtaining consent.

Quality of the professional relationship, continuity of services, etc.

Establishing a relationship of trust between the patient and the health and social care professional is a fundamental ethical obligation, closely linked to the notion of professionalism. Clearly, the act of caring for (or receiving care from) a person is woven into a unique relationship that involves an emotional component and calls upon the human qualities of the healthcare professional, such as empathy, active listening, and understanding of others.

However, in some cases, for budgetary reasons or in the name of pragmatism, there may be a temptation to provide healthcare services through AIS without human intervention with patients (for example, for diagnostic services). In addition, the development of commercial platforms that provide certain health services "on demand", on a one-time basis and without any real ongoing involvement, could potentially lead to a certain detachment from the responsibility of professionals.

It is important to keep a human in the loop when using AI, especially in a sensitive area such as healthcare—some people call this the "right to the human" or the "human guarantee." For example, patients should be able to refuse to "interact" with an AIS under certain circumstances.

Professional independence, integrity, conflicts of interest, etc.

Relationships between healthcare professionals, manufacturers, distributors of various products used in the context of professional practice, and other stakeholders (insurers, employers, etc.) generally need to be regulated to avoid conflicts of interest.

The integration of AIS into professional practice raises the risk that they will be biased toward making diagnoses that are favorable to certain stakeholders (such as disability insurers) or toward recommending certain products (such as drugs). To prevent such a risk, regulation should aim not only to establish that professionals should not use biased AIS, but also to avoid inappropriate connections between clinical professionals and the industry involved in the development of AIS. This is to ensure the necessary clinical objectivity in the care of a patient.

There is also the question of whether or not to use AIS in professional practice. If the use of an AIS is requested by an employer and the professional, based on his or her professional judgment, believes that its use is contrary to the interests of the patient, he should be able to withhold or adapt its use.

Competence ("jurisdiction") over professionals and non-professionals providing services (telehealth, for example)

By their very nature, AIS are likely to be regularly used in the context of telemedicine. Despite its many benefits, telemedicine poses significant legal challenges in determining the applicable law for both professionals and non-professionals providing remote health services, particularly in a cross-jurisdictional context. Indeed, telemedicine creates situations where healthcare professionals and patients may be located in different provinces or even different countries. Given that the rules governing the provision of healthcare services may vary from one province or country to another, determining the applicable laws governing the provision of professional services in telemedicine is a critical issue, particularly in identifying and facilitating available remedies for patients.

Relationships with the regulators, colleagues, and other professionals

Intellectual property rules related to the development of AIS should not impede the review, inspection, and investigation activities of regulatory colleges and other health authorities that are aimed at ensuring the protection of the public. For example, an investigation into a clinical decision made by a professional assisted by an AIS should not be impeded by intellectual property rules applicable to the underlying algorithm. It should be noted that investigators would be bound by confidentiality obligations in this regard.

In the same vein, AIS must remain to some extent interpretable and explainable to avoid the "black box" phenomenon. This phenomenon occurs when it is no longer possible to understand and identify the causes of an undesirable situation or to evaluate the relevance of the tool's use in a professional's practice.

If, in the context of inspections and investigations, it becomes necessary to assess the impact of AIS in a given situation, regulators will need to adequately train their staff (investigators, professional inspection committees, etc.) in this area, or alternatively seek the assistance of experts. The processes involved could then become more complex and costly.

Finally, AIS could prove to be a valuable tool for regulatory colleges and other regulators charged with protecting the public, provided that relevant data is accessible to them. In the Quebec context, this could mean making data from the Ministry of Health and Social Services (MSSS) and the Régie de l'assurance maladie (RAMQ) more accessible to the relevant regulatory colleges to support their activities. In fact, some of this data is already being used by the RAMQ to identify atypical billing patterns. Similarly, AIS powered by relevant data could help detect deviations from generally accepted standards in the professional practices of health professionals, for example in the context of professional inspection processes.

Professional liability insurance and compensation	In health care, the introduction of AIS could lead to new parties being held liable for misdiagnosis or inappropriate treatment, including programmers, designers, manufacturers, and sellers of devices that incorporate AIS. Several liability models overlap, including manufacturer liability, vicarious liability, liability of the institution that purchased the device and is responsible for its maintenance, and liability of the professional who uses it in his or her practice. The legal issues raised may become more complicated if it turns out that it is impossible to explain the recommendations generated by an AIS because of the "black box" nature of the system. Therefore, appropriate measures must be taken to ensure the interpretability of the algorithms underlying AIS.
Management of offices, instrumentation, equipment, etc.	Medical devices incorporating AIS may require an evaluation and approval process to ensure safety, effectiveness and quality prior to its introduction on the market (a process typically under the jurisdiction of Health Canada). In addition, because AIS are inherently non-static (see "machine learning"), there may be a need to ensure periodic validation of the results generated by the device after it is introduced on the market. This responsibility will necessarily be shared with healthcare professionals.
Advertising and public communications	Professionals using AIS may occasionally be tempted to exaggerate their benefits or conceal their limitations in advertising or public communications, in order to increase their customer base or enhance their reputation. Ethical rules in this area should aim to ensure that the information provided by professionals in this regard is trustworthy.
Fees and financial aspects	AIS have the potential to deliver time and efficiency gains, or at least that's the promise. In such cases, the time saved through automation should benefit patients and the public, whether it's through increased access to services or a reduction in their cost, whether publicly or privately funded.

Research

One of the key benefits of AIS is their ability to identify correlations between different variables from large data sets. Using data on genetic profiles, socioeconomic conditions, lifestyle habits, or other factors that may influence an individual's health status, AIS can facilitate the discovery of health determinants or risk factors for disease. Research is therefore crucial, as it enables rapid advances in knowledge and contributes directly to improving healthcare for patients.

One of the risks associated with research is the potential for a competitive climate among researchers and the prioritization of specific economic interests over the public interest. For example, one could imagine a scenario in which certain rules are disregarded because there could be significant profits to be made from bringing an AIS to market quickly, even if it hasn't been sufficiently tested or proven, or if it has a bias toward prescribing certain drugs or products.

To avoid these undesirable effects, clear ethical standards for research must be established to address conflicts of interest. Ethical standards are also needed to ensure the interpretability and explainability of AIS.

In the context of data collection, certain questions arise: "How will patients be involved? "How can their rights be respected, especially with regard to consent and privacy?" Researchers should certainly consider the potential future uses of the data they collect and include this dimension in the consent of research participants. It would also be preferable for machine learning developers to be trained in ethical and social issues.

There are two opposing schools of thought on data sharing. While some propose the development of research infrastructures that respect personal data, others favor the idea of a "data commons" and call on governments to support research by developing data sharing standards.